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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/330,215 | 06/11/99 | PORTA | R P8907-9014 |
| EXAMINER | | | |

HM22/0915
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| | |
|------------|--------------|
| KISHORE, G | PAPER NUMBER |
| ART UNIT | 6 |

1615

DATE MAILED: 09/15/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3- month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☒ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) 485
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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DETAILED ACTION

The preliminary amendment dated 6-11-99 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

1. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

‘preferably’ in claim 1 is indefinite (also in claim 8-13) since it is unclear whether the limitation following this term is indeed the limitation. ‘medicament’ without stating what the disease is, is not meaningful.

It is unclear how the administration of the composition of claim 1 results in the sustained release of endothelial prostacyclin as recited in claims 5 and 18.

It is unclear whether the compounds recited in claim 9 are present in addition to the liposome forming lipids.

It is unclear whether the terms used in parenthesis in claim 11 are indeed the limitations. If they are, they should be recited without the parenthesis. ‘the phosphatidylcholine’ in this claim lacks antecedent basis in the parent claim.

2. Claims 15-18 provide for the use of the complexes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant

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is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in combination with Litzinger (BBA, 1996) of record by itself or in further combination with Maccarone (BBRC, 1992), Eastman (Human Gene Therapy, 1997) individually or in combination.

Applicant indicates on pages 3-7 of the specification that instant polynucleotides are known for their function.

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Litzinger while disclosing formulations containing cationic liposomes and their complexes with polynucleotides teaches that oligonucleotides have the inability to efficiently traverse through cellular membranes and hence complexation with cationic liposomes (note the abstract and page 140).

Maccarone teaches that DNA when complexed with cationic liposomes are able to transfect protoplasts (note the abstract).

Similarly, Eastman teaches that the complex prepared by the addition of cationic liposomes and DNA has an efficient transfection ability (note the abstract and Materials and methods).

The use of cationic liposomes for the delivery of art known polynucleotides would have been obvious to one of ordinary skill in the art in view of Litzinger's teachings that oligonucleotides do not have the ability to cross cellular membrane, but are able to efficiently transfect when complexed with cationic liposomes as also shown by Maccarone and Eastman.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 13, 2000